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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,930	10/11/2001	Michael Poirier	560.09-US1	4572
34284	7590	04/20/2006	EXAMINER	
ROBERT D. FISH RUTAN & TUCKER LLP 611 ANTON BLVD 14TH FLOOR COSTA MESA, CA 92626-1931			LAM, ANN Y	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/977,930

Applicant(s)

POIRIER ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-10 and 12-14 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 6, 2006 has been entered.

### ***Status of Claims***

Claims 1-6 have been cancelled. New claims 7-14 have been added and are now pending.

### ***Specification***

The disclosure is objected to because of the following informalities: a brief description of the drawing is missing.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12, line 2, recites "the conduits". There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-10 and 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Southgate et al., 5,863,502.

As to claim 7, Southgate et al. disclose a method of continuously separating whole blood, comprising:

providing a container having a flexible top sheet (i.e., flexible upper film, col. 11, lines 46-47 and col. 12, lines 42-43, and col. 10, line 59), a fluid receiving port (i.e., port near 143A in fig. 5a, and see col. 16, line 63), a fluid discharge port (i.e., port

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near 143B in fig. 5a, and see col. 16, lines 63-64), and a plurality of compartments (see col. 12, line 16 and 39-44, disclosing a plurality of reaction compartments between upper film 110 and lower film 120) fluidly coupled to at least one of the fluid receiving port and the fluid discharge port (see ports, i.e., openings, near 143A and 143B in fig. 5A, and col. 16, lines 63-64);

introducing a continuous flow of whole blood into the fluid receiving port while at the same time emitting a continuous flow of processed whole blood that is at least partially depleted of target antigen (col. 16, lines 62-64);

wherein the target antigen (col. 30, line 60-64, and col. 31, lines 18-36, disclosing an antibody attached to a solid support) is separated from the whole blood (col. 28, lines 61-62) within at least one of the plurality of compartments using a magnetic force (col. 26, lines 21-39) and an automatic mechanical force (see col. 19, lines 50-53, disclosing a device for pumping each reaction chamber 160; col. 23, lines 13-18, disclosing several pumping mechanisms that can be utilized with the invention), wherein at least one of the magnetic force and automatic mechanical force is transmitted through the flexible top sheet (col. 26, lines 25, lines 65-66, disclosing magnets brought adjacent to the device; see also col. 23, lines 13-18, disclosing a roller or plungers pressing on the flexible film of the fluid chamber);

wherein a plurality of actuators in a device retaining the container compress at least some of the compartments in a predetermined manner to thereby move the whole blood and the processed whole blood through the plurality of compartments (see col. 19, lines 50-53, disclosing a device for pumping each reaction chamber 160; col. 23,

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lines 13-18, disclosing several pumping mechanisms that can be utilized with the invention.)

As to claim 8, the container is fabricated from a flexible top sheet and a flexible bottom sheet (col. 11, lines 47-48 and col. 12, lines 16 and lines 39-44).

As to claim 9, a plurality of compartments and fluid conduits that fluidly couple one compartment to another compartment are formed by the top and bottom sheets (col. 12, lines 16 and lines 39-44).

As to claim 10, at least one of the compartments further includes a port that allows draining of the at least one of the compartments (i.e., one of the other compartments disclosed in col. 12, lines 16 and lines 39-44, which has a port for draining from the compartments, such as disclosed in col. 16, line 63).

As to claim 12, at least one of the compartments or at least one of the conduits that fluidly couple the compartments is configured such that an actuator can compress the conduit to partially or completely stop flow of the whole blood or processed whole blood through the conduit (see col. 16, lines 64-67).

As to claim 13, at least one of the compartments includes a fluid, specifically a buffer (col. 15, lines 18-19).

As to claim 14, the affinity marker is antibody (col. 30, line 60-64, and col. 31, lines 18-36, disclosing an antibody attached to a solid support).

***Allowable Subject Matter***

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach a method comprising providing a container with a plurality of compartments and introducing a continuous flow of whole blood into a port while at the same time emitting a continuous flow of processed whole blood that is at least partially depleted of a target antigen, using a magnetic force and an automatic mechanical force, and a plurality of magnetic beads in at least one of the compartments, wherein the entire container is flexible. The container in the Southgate reference has elements that do not make the entire container flexible (Fig. 5A for example).

***Response to Arguments***

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection. (The reference Robinson et al. is no longer used as a grounds for rejection due to the amendments to the claims.)

***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 4/14/06  
Ann Lam